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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/005,318	01/09/98	HEIN M	3100954401C1

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EXAMINER	
ROMEO,D	

ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/005,318	Applicant(s) Hein et al.
	Examiner David S. Romeo	Group Art Unit 1646

☒ Responsive to communication(s) filed on *1-9-98* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-41* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-41* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

The claims are drawn to a disparate and patently distinct targeting molecules linked to a biological agent. For each of targeting molecule there are six patentably distinct biological agents recited in claims 30 and 40 as follows:

a. an enzyme, classified in class 435, subclass 183.

b. a binding agent of indeterminable constitution, classification dependent upon binding agent.

c. an inhibitor of indeterminable constitution, classification dependent upon inhibitor.

d. a nucleic acid, classified in class 536, subclass 22.1.

e. a carbohydrate, classified in class 536, subclass 1.11.

f. a lipid, classified in class 554, subclass 1.

Groups I-VI are encompassed by a targeting molecule linked to a biological agent a.-f., respectively.

2. The inventions are distinct, each from the other because of the following reasons:

The following pairwise combinations of products are independent and distinct, wherein neither member of a pair is required for the production or use of the other, and wherein each of

the pair can be manufactured independently of the other and used for independent and distinct purposes: I and each of II-VI; II and each of III-VI; III and each of IV-VI; IV and each of V and VI; V and VI.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, require separate searches and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 32 and 33, encompass six patentably distinct methods of treating a patient afflicted with a disease by administering a targeting molecule of groups I-VI above, classified as follows:

a. an enzyme, classified in class 424, subclass 94.1.

b. a binding agent of indeterminable constitution, classification dependent upon binding agent.

c. an inhibitor of indeterminable constitution, classification dependent upon inhibitor.

d. a nucleic acid, classified in class 514, subclass 44.

e. a carbohydrate, classified in class 514, subclass 23.

f. a lipid, classified in class 424, subclass 283.1.

For each method of treatment of claims 32-35 there are 12 distinct diseases to be treated, as follows:

g. cancer

h. viral infection

i. inflammatory disorders

j. autoimmune disorders

k. asthma

l. celiac disease

m. colitis

n. pneumonia

o. cystic fibrosis

p. bacterial infection

q. mycobacterial infection

r. fungal infection

Groups VII-LXXVIII are represented by combinations of a.-f. and g.-r.

Claims 34 and 35, encompass six patentably distinct methods of inhibiting the development of a disease by administering a targeting molecule linked to:

s. an enzyme, classified in class 424, subclass 94.1.

t. a binding agent of indeterminable constitution, classification dependent upon binding agent.

u. an inhibitor of indeterminable constitution, classification dependent upon inhibitor.

v. a nucleic acid, classified in class 514, subclass 44.

w. a carbohydrate, classified in class 514, subclass 23.

x. a lipid, classified in class 424, subclass 283.1.

For each of the method of inhibiting the development of a disease there are 12 distinct diseases to be inhibited, as follows:

y. cancer

z. viral infection

aa. inflammatory disorders

bb. autoimmune disorders

cc. asthma

dd. celiac disease

ee. colitis

ff. pneumonia

gg. cystic fibrosis

hh. bacterial infection

ii. mycobacterial infection

jj. fungal infection

Groups LXXVIII-CL are represented by combinations of s.-x. and y.-jj.

Groups VII-LXXVIII and Groups LXXVIII-CL are patentably distinct inventions because treating a pathology and inhibiting the development of a pathology do not share the same inventive concept because treating is directed toward the effecting an extant pathology whereas inhibiting is directed toward avoiding the occurrence of a pathology.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, require separate searches and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Inventions I-VI and inventions VII-CL are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of labeling or marking the basolateral surface of an epithelial cell.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, require separate searches and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Claims in groups I-CL are generic to a plurality of disclosed patentably distinct species of linkage of the targeting molecule and the biologic agent comprising covalent linkage and noncovalent linkage. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Claims in groups I-CL are generic to a plurality of disclosed patentably distinct species of covalent linkages comprising glycoside bond, phosphodiester bond, substrate for intracellular enzyme, substrate for extracelluar enzyme, or one of the linkages at paragraph bridging pages 17-18 through paragraph bridging pages 22-23. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. For each of said covalent linkages that is either a substrate of an intracellular enzyme or the substrate of an extracelluar enzyme, claims I-CL are generic to a plurality of disclosed patentably distinct species comprising the species recited in claim 37, or one of the proteases at paragraph bridging pages 17-18 through paragraph bridging pages 22-23.. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Claims in groups I-CL are generic to a plurality of disclosed patentably distinct species comprising the biological agents listed at page 7, full paragraph 3; page 23, full paragraph 1, through page 30, full paragraph 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday from 6:45 a.m. to 3:15 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242.

Faxed draft or informal communications should be directed to the examiner at (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID ROMEO
PATENT EXAMINER

June 19, 1999